

**AMENDMENTS TO THE CLAIMS**

1.-20. (Cancelled)

21. (New) A method of test strip qualification comprising:  
providing a test strip comprising an assay reaction area, a first control reaction area and a second control reaction area;  
obtaining PT results for each reaction area; and  
comparing results from said control reaction area to control qualification criteria comprising an upper limit and a lower limit, wherein said upper limit is dependent upon assay reaction area PT results at or below about a 2.0 International Normalized Ratio (INR) and wherein said upper limit comprises a value independent of assay reaction area PT result for assay reaction area PT results at or above about a 2.0 INR, wherein said test strip is qualified if said results fall below within said lower limit and said upper limit.

22. (New) The method of claim 21, wherein said lower limit comprises a value independent of assay reaction PT results.

23. (New) The method of claim 22, wherein said lower limit is about 0.60 INR.

24. (New) The method of claim 21, wherein said upper limit is a line function when said assay reaction area PT results are at or above about a 2.0 INR.

25. (New) The method of claim 24, wherein said line function is expressed as  $y=mx+b$ , wherein  $y$  represents INR results obtained for said control reaction area,  $x$  represents INR results obtained for said assay reaction area,  $m \approx 0.50$  and  $b \approx 0.91$  for said upper limit.

26. (New) The method of claim 21, further comprising outputting a message to a user indicating test strip qualification.

27. (New) A method of test strip qualification comprising:

providing a test strip comprising an assay reaction area, a first control reaction area and a second control reaction area;

obtaining PT results for each reaction area; and

comparing results from said control reaction area to control qualification criteria comprising an upper limit and a lower limit, wherein said upper limit is dependent upon assay reaction area PT results and wherein said lower limit comprises first and second portions dependent upon assay reaction area PT results, wherein said second portion drops-off from said first section, wherein said test strip is qualified if said results fall within said upper limit and said lower limit.

28. (New) The method of claim 27, further comprising outputting a message to a user indicating test strip qualification.

29. (New) A method of test strip qualification comprising:

providing a test strip comprising an assay reaction area, a first control reaction area and a second control reaction area;

obtaining PT results for each of said reaction areas; and

comparing results from said control reaction area to control qualification criteria comprising an upper limit and a lower limit, wherein said upper limit is dependent upon assay reaction area PT results at or below about a 2.0 International Normalized Ratio (INR) and wherein said upper limit comprises a value independent of assay reaction area PT result for assay reaction area PT results at or above about a 2.0 INR, wherein said test strip is qualified if said results fall below within said lower limit and said upper limit; and

comparing results from said control reaction area to control qualification criteria comprising an upper limit and a lower limit, wherein said upper limit is dependent upon assay reaction area PT results and wherein said lower limit comprises first and second portions dependent upon assay reaction area PT results, wherein said second portion drops-off from said first section, wherein said test strip is qualified if said results fall within said upper limit and said lower limit;

wherein said test strip is qualified if said results from said first control reaction area fall within said first upper limit and said first lower limit and if said results from said second control reaction area fall within said second upper limit and said second lower limit.

30. (New) The method of claim 29, further comprising outputting a message to a user indicating test strip qualification.

31. (New) A system programmed to operate according to a method selected from the test strip qualification methods of claims 21, 27 or 29.

32. (New) A computer-readable medium embodying a program to direct a system to perform a method selected from the test strip qualification methods of claims 21, 27 or 29.

33. (New) A computer-readable medium containing data representing sample results, wherein said data is made by a method selected from the test strip qualification methods of claims 21, 27 or 29.